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## 5.0 510(k) SUMMARY

SEP 1 6 2008

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the Product Line Extension to the *Octane*™ Vertebral Body Replacement System:

### 5.1 Submitted By:

VertiFlex®, Incorporated
1351 Calle Avanzado
San Clemente, California 92673
Contact: Steve Reitzler, Vice President of Regulatory & Quality Assurance

Date Prepared: August 8, 2008

### 5.2 Device Name

| | |
|---|---|
| Trade or Proprietary Name: | *Octane*™ Intervertebral Body Fusion Device<br>*Octane*™ Vertebral Body Replacement |
| Common or Usual Name: | Intervertebral body fusion device<br>Vertebral body replacement |
| Device Classification: | §888.3080, Intervertebral body fusion device;<br>Product Code MAX<br>§888.3060, Spinal intervertebral body fixation orthosis;<br>Product Code MQP |

### 5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate device:

*Octane*™ Vertebral Body Replacement System – (VertiFlex®, Inc.; K070218)

### 5.4 Device Description

Like the predicate *Octane*™ Vertebral Body Replacement System, or *Octane*™ *VBR* System, the *Octane*™ device that is the subject of this "Special" 510(k) submission is an implant composed of pure Poly(Etheretherketone), or PEEK OPTIMA®, Grade LT1. When used as a vertebral body replacement, the device is intended to serve as a partial or total replacement of a vertebral body that is collapsed, damaged, or unstable as a result of tumor or trauma (i.e., fracture). When used as an intervertebral body fusion device, the device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). As a vertebral body replacement, the device is intended for use with allograft or autograft, and as an intervertebral body fusion device, it is intended for use with autogenous bone graft.

*Octane*™ implants are available in a range of sizes and shapes, to accommodate different surgical approaches and anatomical needs, and may be implanted by either conventional surgical methods, or via minimally-invasive techniques.

## 5.5 Intended Use

**When used as a vertebral body replacement:**
The *Octane*™ device is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The *Octane*™ device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. The *Octane*™ device may be used with allograft or autograft.

**When used as an intervertebral body fusion device:**
The *Octane*™ device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least 6 months of non-operative treatment. The *Octane*™ device is intended to be used with autograft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

## 5.6 Comparison to Predicate Devices

In accordance with the agency guideline entitled *The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications* (March 1998), VertiFlex® has established, through rigorous design control processes conforming to 21 CFR §820.30, and a comprehensive risk analysis, that the subject Product Line Extension to the *Octane*™ System is substantially equivalent to the commercially-available predicate *Octane*™ VBR System. Further, these modifications (a) do not alter the fundamental technological principles of the device, and (b) continue to meet all design input requirements.

## 5.7 Summary of Non-Clinical Tests

Such verification and validation tests as were identified as appropriate to address the results of a risk analysis for the subject Product Line Extension to the *Octane*™ VBR System were completed, and all acceptance criteria were met.

## 5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

## 5.9 Conclusions

The results of all design, risk analysis, and verification and validation activities support the substantial equivalence of the subject Product Line Extension to the predicate *Octane*™ VBR System, and establish that the subject device continues to meet all design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 6 2008

Vertiflex Incorporated
% Mr. Steve Reitzler
VP, Regulatory & Quality Assurance
1351 Calle Avanzado
San Clemente, California 92673

Re: K082270
Trade Name: Octane™ Vertebral Body Implant System
Regulation Number: 21 CFR 888.3080
Regulation Names: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: September 9, 2008
Received: September 10, 2008

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K082270

Device Name: *Octane*™ Vertebral Body Implant System

Indications for Use:

***When used as a vertebral body replacement:***
*The* Octane™ *device is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The* Octane™ *device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. The* Octane™ *device may be used with allograft or autograft.*

***When used as an intervertebral body fusion device:***
*The* Octane™ *device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least 6 months of non-operative treatment. The* Octane™ *device is intended to be used with autogenous graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.*

FOR M. MEEKERSON

(Division Sign-Off)
**Division of General, Restorative, and Neurological Devices**

510(k) Number K082270

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)